

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTERVET, INC. and
BTG INTERNATIONAL LIMITED,

Plaintiffs,

v.

MERIAL LIMITED,

Defendant.

Civil Action No. 05-887-KAJ

**OPENING BRIEF IN SUPPORT OF
DEFENDANT MERIAL LIMITED'S MOTION
TO STAY THE LITIGATION PENDING REEXAMINATION**

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NATURE AND STAGE OF PROCEEDINGS.

Plaintiff Intervet, Inc. (“Intervet”) filed, but did not serve, its initial complaint for infringement of U.S. Patent No. 5,587,166 (the “166 patent”) on Merial Limited (“Merial”) on December 23, 2005. Merial requested that the United States Patent and Trademark Office (“USPTO”) reexamine the ’166 patent on March 8, 2006, which request was granted on April 5, 2006. Intervet and co-plaintiff BTG International Limited (“BTG”) filed an Amended Complaint (the “Amended Complaint”) on April 11, 2006, again asserting that Merial infringes the ’166 patent. Merial is filing its Answer, Affirmative Defenses and Counterclaims concurrently with this Motion to Stay.

SUMMARY OF ARGUMENT

1. Defendant Merial moves for a stay of this patent infringement action by Plaintiffs Intervet and BTG (collectively “Plaintiffs”). As ordered by the USPTO, the patent-in-suit, *i.e.*, the ’166 patent, is the subject of U.S. Reexamination Proceeding Serial No. 90/007,964 (“the Reexamination”). Three factors guide courts in determining whether to grant a stay pending reexamination: (i) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (ii) whether a stay would simplify the issues in question and thereafter the trial of the case; and (iii) whether discovery is complete and a trial date has been set. All of these factors favor a stay of this litigation until there is a final decision in the Reexamination.

2. The grounds for a stay of this case are compelling because the USPTO has already: (i) cited thirteen prior art documents against the claims of the ’166 patent, including prior art that was *not* before the Examiner during original prosecution, and (ii) identified eleven substantial new questions of patentability as to *all* of the claims of the ’166 patent. Thus, serious and substantial questions of patentability surround the ’166 patent. These substantial questions

of patentability are pending before the USPTO and warrant a stay of this action pending the final decision by the USPTO in the Reexamination.

STATEMENT OF FACTS

A. Factual And Procedural Background With Respect To This Litigation.

Pasteurella pneumonia costs U.S. beef and dairy cattle producers hundreds of millions of dollars each year due to treatment costs, reduced production, and animal death. To address this significant problem, Merial introduced RESPISHIELD® HM on September 24, 2004. RESPISHIELD® HM is a ready-to-use vaccine for beef and dairy cattle. A single dose of RESPISHIELD® HM confers immunity, and prevents pneumonia in beef and dairy cattle. Thus, RESPISHIELD® HM is an important product that prevents significant losses to beef and dairy cattle producers, and that prevents the suffering of animals.

Approximately one year after the introduction of RESPISHIELD® HM, Intervet sent a letter to Merial concerning RESPISHIELD® HM and the '166 patent. Before Merial replied to that letter, Intervet filed on December 23, 2005, but did not serve, a complaint against Merial alleging infringement of the '166 patent.¹ Representatives of the parties met on February 14, 2006, in an effort to resolve the issues raised in Intervet's complaint. When that effort proved to be unsuccessful, Merial filed a Request For Reexamination of the '166 patent with the UPSTO on March 8, 2006. On April 5, 2006, the USPTO Ordered reexamination of the '166 patent, citing thirteen prior art documents and finding eleven substantial new questions of patentability.

¹ Since the original complaint failed to join BTG, whom Plaintiffs now allege is the assignee of the '166 patent, as a co-plaintiff, the original complaint was defective and failed to confer jurisdiction on this Court. *See Waterman v. McKenzie*, 138 U.S. 252, 255 (1891) (holding that only an owner or assignee of a patent can bring suit for its alleged infringement); *see also Sicom Sys. Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 976 (Fed. Cir. 2005) (explaining that a licensee of a patent without "all substantial rights" cannot alone sue for infringement).

Despite the Reexamination (and the initial citation of thirteen prior art documents and the identification of eleven substantial new questions of patentability by the USPTO), Plaintiffs filed the Amended Complaint on April 11, 2006. The Amended Complaint named both Intervet and BTG as plaintiffs, and asserted as its sole cause of action infringement of the '166 patent by Merial. This case is therefore in its infancy. Merial filed its Motion to Stay concurrently with its Answer, Affirmative Defenses, and Counterclaims. Discovery has not commenced, nor has either party served Rule 26(a)(1) initial disclosures. The Court has not set a trial date.

B. Reexamination Proceedings: A Vehicle For Patentability Determinations.

The Patent Act allows any person to file with the USPTO a request for reexamination of any patent claim on the basis of any prior art. 35 U.S.C. § 302. The USPTO grants those requests that present “a substantial new question of patentability affecting any claim of the patent” 35 U.S.C. § 303(a). If a substantial new question of patentability is found as to one claim, all claims will be reexamined during an *ex parte* reexamination process. *See* Manual of Patent Examining Procedure § 2216 (8th ed. 2005).

Reexamination proceedings were designed by Congress to ““permit efficient resolution of questions about the validity of issued patents without recourse to expensive and lengthy infringement litigation.”” *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426 (Fed. Cir. 1988) (quoting H. Rep. 1307(1)(1980) (as reprinted in 1980 U.S.C.C.A.N. 6460, 6463)). Congress also mandated that the USPTO handle the reexamination proceedings with “special dispatch.” *Id.* Thus, reexamination is a vehicle provided by Congress for “an efficient and relatively inexpensive” review of the validity of patents. *Id.*

After completing reexamination, the USPTO will issue a certificate: (i) canceling any claim deemed unpatentable, (ii) confirming any claim deemed patentable, or (iii) issuing new or

amended claims based on its reexamination. 35 U.S.C. § 307(a). As a result, reexamination proceedings can be particularly useful because they either eliminate the trial of validity issues (when claims are cancelled in reexamination) or facilitate the trial of those issues by providing the district court with the USPTO's guidance with respect to the validity of the patent (when a claim survives reexamination). *See Gould v. Control Laser Corp.*, 705 F.2d 1340, 1342 (Fed. Cir. 1983). As explained by the Federal Circuit in another case:

[T]he intent underlying reexamination is to "start over" in the PTO with respect to the limited examination areas involved, and to *re* examine the claims and to *examine* new or amended claims, as they would have been considered if they had been originally examined in light of all of the prior art of record in the reexamination proceeding.

In re Etter, 756 F.2d 852, 857 (Fed. Cir. 1985) (emphasis in original).

ARGUMENT

I. The Court Has Inherent Power To Stay Litigation Pending Reexamination.

Courts have inherent power to manage their dockets and stay proceedings, including the authority to order a stay pending conclusion of a USPTO reexamination. *Landis v. North Am. Co.*, 299 U.S. 248, 254-55 (1936) (a court has inherent power to stay proceedings in control of its calendar). *See also Ethicon*, 849 F.2d at 1426-27; *Alloc, Inc. v. Unilin Decor NV*, No. 03-253, 2003 WL 21640372, at *2 (D. Del. July 11, 2003); *Pegasus Dev. Corp. v. DirectTV, Inc.*, No. 00-1020, 2003 WL 21105073, at *1 (D. Del. May 14, 2003); *Harry W. Eberle v. Harris*, No. 03-5809, 2005 U.S. Dist. LEXIS 31885, at *6 (D.N.J. Dec. 7, 2005); *PIC, Inc. v. Prescon Corp.*, 77 F.R.D. 678, 681-682 (D. Del. 1977) (granting stay while patent in suit subject of USPTO reissue proceeding); Donald S. Chisum, *Chisum on Patents*, § 11.07[4][b][iv][B] at 11-728 - 29 (2005 ed.). Further, "in passing legislation establishing the reexamination proceeding, Congress stated

its approval of district courts liberally granting stays within their discretion." *Emhart Indus. Inc. v. Sankyo Seiki Mfg. Co.*, 3 U.S.P.Q. 2d 1889, 1890 (N.D. Ill. 1987).

II. The Court Should Exercise Its Discretion And Stay This Litigation.

As noted above, three practical factors control whether a stay pending reexamination should be granted:

- Whether the stay will prejudice or present a clear tactical disadvantage to the non-moving party,
- Whether the stay will simplify the issues to be tried, and
- Whether discovery has been completed and a trial date set.

Alloc., 2003 WL 21640372, at *2; *Pegasus*, 2003 WL 21105073, at *1; *Eberle*, 2005 U.S. Dist. LEXIS 31885, at *6. Each of these factors warrants a stay of this litigation.

A. Plaintiffs Will Suffer No Prejudice If The Court Stays This Litigation.

Staying the present litigation poses no prejudice or tactical disadvantage to Plaintiffs. Merial timely invoked its legal right to the reexamination procedure, and the USPTO has determined that reexamination is warranted. *See, Gioello Enters. Ltd. v. Mattel, Inc.*, No. C.A. 99-375 GMS, 2001 WL 125340, at *2 (D. Del. 2001); *Pegasus*, 2003 WL 21105073, at *3 (filing request for reexamination years after commencement of suit did not evidence undue delay).

Indeed, the peculiar facts of this case clearly demonstrate that a stay poses no prejudice or tactical disadvantage to Intervet or BTG. Plaintiffs filed their Amended Complaint² after the USPTO had already ordered reexamination of the '166 patent based on thirteen prior art references and eleven substantial new questions of patentability. Thus, Plaintiffs knew that the '166 patent was subject to reexamination and that it faced substantial questions of patentability

² Intervet's original complaint was never served and was defective on its face because it did not name BTG as a plaintiff. *See n.1, supra*.

before they filed their Amended Complaint. Under these circumstances, Plaintiffs had to realize that there was every likelihood Merial would request a stay of this litigation. Accordingly, Merial created no tactical advantage by filing for reexamination, especially since Merial requested reexamination prior to the commencement of the current litigation. Knowing that their patent was in reexamination, and that Merial would likely file a motion to stay, Plaintiffs can hardly claim prejudice. *See Cygnus Telecomm. Tech. LLC v. United World Telecom L.C. (In re Cygnus Telecomm. Tech., LLC, Patent Litig.*, 385 F. Supp. 2d 1022, 1023 (N.D. Cal. 2005) (explaining that time it took USPTO to conduct reexamination did not constitute prejudicial delay).

B. A Stay Will Simplify The Issues For The Court.

Many courts have recognized the benefits of staying a patent infringement action until there is a final decision in a reexamination. Among these benefits are:

(1) many discovery problems relating to the prior art may be alleviated; (2) the record of the reexamination would likely be entered at trial, reducing the complexity and length of the litigation; (3) the issues, defenses, and evidence will be more easily limited in pre-trial conferences following a reexamination; (4) the outcome of the reexamination process may encourage a settlement without further involvement of the court; and (5) if the patent is declared invalid, the suit will likely be dismissed as to that patent.

Pegasus, 2003 WL 21105073, at * 2 (emphasis added); *accord Alloc*, 2003 WL 21640372, at *2; *see also Ethicon*, 849 F.2d at 1426. As the *Pegasus* Court further explained:

These efficiencies will result in a reduced cost of litigation for the parties and more effective utilization of the limited resources of the court. . . . Thus, a stay may result in a simplification or reduction of issues for the court's consideration, or it may dispense with the litigation entirely. These are considerable economies indeed.

Pegasus, 2003 WL 21105073, at *2. Moreover, courts favor staying litigation where, as here, there is only one patent at issue. *See Eberle*, 2005 U.S. Dist. LEXIS 31885, at *8 n.1 (D.N.J.

2005) ("A clearer line of site for staying a case pending PTO reexamination exists when it is only a single patent case.").

Merial submits that this Court should "find particular merit in permitting an additional layer of review by the USPTO before expending any further judicial resources," especially in light of the extensive original prosecution of the '166 patent,³ and "the PTO's conclusion that all of the challenged claims warrant reexamination." *Pegasus*, 2003 WL 21105073, at *2; *see also In re Cygnus Telecomms. Tech., LLC*, 385 F. Supp. 2d at 1023 ("A stay is particularly justified where the outcome of the reexamination would be likely to assist the court in determining patent validity and, if the claims were canceled in the reexamination, would eliminate the need to try the infringement issue."); *Digital Magnetic Sys., Inc. v. Ainsley*, 213 U.S.P.Q. 290, at 290 (W.D. Okla. 1982) ("Congress enacted the reexamination procedure to provide an inexpensive, expedient means of determining patent validity which . . . should be deferred to by the courts."); *Softview Computer Prods. Corp. v. Haworth, Inc.*, No. 97-8815, 2000 WL 1134471, at *3 (S.D.N.Y. Aug. 10, 2000) ("[T]he grant of a stay will maximize the likelihood that neither the Court nor the parties expend their assets addressing invalid claims.")

In view of the judicial economy and litigation cost savings that will be provided by a stay until the final decision in the Reexamination, this Court should exercise its discretion and stay this action.

³ Applications that resulted in the '166 patent were pending before the USPTO for more than eight years. Specifically, the '166 patent issued December 24, 1996 from U.S. application Serial No. 427,692, filed April 24, 1995 as a continuation of U.S. application Serial No. 106,720, filed August 16, 1993, which was a continuation of U.S. application Serial No. 168,960, filed March 16, 1988. There was thus an extensive original prosecution of the '166 patent that the parties and the Court have yet to wade through in this litigation.

C. Nothing Yet Has Occurred In This Litigation.

The third factor in determining whether to grant a stay is the status of the litigation, *i.e.*, how much discovery has been conducted and whether the court has set a trial date. *Alloc*, 2003 WL 21640372, at *3. This case has just begun. Merial today filed its Motion to Stay concurrently with its Answer, Affirmative Defenses and Counterclaims.⁴ Discovery has not started. Neither party has served Rule 26(a)(1) initial disclosures. There is no discovery schedule, and the Court has not set a trial date. These facts strongly support this Court's granting Merial's Motion to Stay until there is a final decision in the Reexamination. *Id.* ("[T]he stay will be entered before any party incurs substantial litigation-related expenses.")

⁴ Merial's counterclaims are for declaratory judgments that the '166 patent is not infringed, is invalid and is unenforceable. These are compulsory counterclaims under Fed. R. Civ. P. 13(a), and their inclusion in Merial's Answer does not mitigate against granting Merial's Motion to Stay. *See Eberle*, 2005 U.S. Dist. LEXIS 31885, at *2 (stay granted when counterclaims for invalidity and unenforceability pending).

CONCLUSION

For the reasons set forth herein and on the authorities cited, Merial respectfully requests that the Court grant Merial's Motion to Stay this litigation until there is a final decision in the Reexamination.

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